

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

Griffith Hack
GPO Box 3125
BRISBANE QLD 4001

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference BJN:MR:FP20447		Date of mailing (day/month/year) 1 0 NOV 2004	
International application No. PCT/AU2004/001399		FOR FURTHER ACTION See paragraph 2 below	
International filing date (day/month/year) 13 October 2004	Priority date (day/month/year) 13 October 2003		
International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ C12Q 1/68			
Applicant BIONOMICS LIMITED et al			

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer TERRY MOORE Telephone No. (02) 6283 2632
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------

BEST AVAILABLE COPY

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/001399

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/001399

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application☒ claims Nos: **8 in part**

because:

☐ the said international application, or the said claim Nos.relate to the following subject matter which does not require an international preliminary examination (*specify*):☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.
are so unclear that no meaningful opinion could be formed (*specify*):☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed.☒ no international search report has been established for said claims Nos. **8 in part, see "observations"**☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished☐ does not comply with the standard

the computer readable form

☐ has not been furnished☐ does not comply with the standard☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/001399

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 11-13, 18-23 and 27	YES
	Claims 1-10, 14-17 and 24-26	NO
Inventive step (IS)	Claims	YES
	Claims 1-27	NO
Industrial applicability (IA)	Claims 1-27	YES
	Claims	NO

2. Citations and explanations:

The specification discloses the linkage between benign familial infantile seizures and mutations in the SCN2A gene. It also discloses that this information can be used in conjunction with existing information about the linkage between the KCNQ2 and KCNQ3 genes and benign familial neonatal seizures to distinguish between these different types of epilepsy.

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 Heron et al (2002) The Lancet 360, 851-2
D2 Mulley et al (2003) Current Opinion in Neurology 16, 171-6
D3 WO 2003 008574

Novelty and Inventive Step

Berkovic et al (2004) is not discussed here because the citation was published after the priority date of the application.

Both D1 and D2 disclose methods of identifying individuals with BFNIS by amplifying regions of the SCN2A gene and identifying mutations in the gene following electrophoresis and sequencing. Each citation also discloses diagnosis of BFNIS by identifying mutations in the KCNQ2 and/or 3 genes. As such both citations fully disclose the methods of claims 1-10, 14-17 and 24-26, thereby depriving these claims of novelty and an inventive step. With respect to the remaining claims, which define other well known methods of identifying and characterising genetic mutations, these additional features are standard alternatives to the methods disclosed in the citations. As such, these claims lack an inventive step in light of each of the citations.

Although D3 also discloses methods of diagnosing epilepsies, including benign familial epilepsies by detecting mutations in the SCNA genes. The citation does not provide a direct link between BFNIS in particular and SCNA2. As such the citation represents background art that does not clearly impact on the novelty or inventive step of the claims.